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Letters to the Editor

To the Editor

I am writing this letter to the editor to object to a number of claims made in the article by T. G. Tunevall, "Postoperative Wound Infections and Surgical Face Masks: A Controlled Study," World J. Surg. *15*:383, 1991. Briefly, my objections are:

1. The title states that the study is a controlled one. Having spent many years of research in the surgical environment, I believe this is as *un*controlled a study as I have seen. The report would have been more palatable if it had been called an uncontrolled, or partially controlled study, rather than a controlled one. Simply stating that the patient characteristics and types of operation were similar in two groups neglects the endogenous, exogenous, and environmental factors that have been shown to make all the difference. Just a few of the factors neglected by the author in his "control", all of which are known by a voluminous body of evidence to have some effect on the incidence of wound infection, are: duration of operative procedure; condition or resistance of the patient (i.e., receiving cytotoxic or corticoid drugs, radiation therapy, concommitant disease, or the very young or very old); identification of endogenous pathogens (patient's skin, organ, or tissue infections); identification of surgical team's pathogens (skin, nasopharynx, etc); ICU versus non-ICU pre- or postoperative stay; foreign body implant (joint, vascular, or other prosthesis); surgical technical errors, and so on.

2. In fact, one is hard pressed to find what *is* controlled in this study, other than that the operations were performed in the same operating rooms. Certainly, the personnel were not controlled. By the authors' admission, no less than 250 people took part, among which teams of 8 people, not necessarily the same people, were present at each operation. There was no control on the amount of talking, laughing, or coughing at each operation, other than a rough estimate that it was "about the same" at all operations in both groups. It was apparently a decision by judgment that masks be worn by surgeons "who had colds". But no cultures were taken of face skin, hair, nasopharynx, or any other potential exogenous source, to seek a possible match between wound bacteria and their actual source whether the participants wore masks or not, or whether they had colds or not. Nor were other potential endogenous sources controlled.

3. The study was "designed to reveal any 30% or greater difference in wound infection rates using face masks or not . . . Any difference less than 30% would be impossible to verify *from the number of operations performed*" (around 2,000 per year). This is a factitious paradigm which can skew the results in favor of finding that masks were of no value. In other words, this arbitrary condition, hardly a control, was based on reference to a previously published report that purported to show a 50% decrease in wound infection rates when surgical masks were not worn. This shaky premise certainly cannot justify any conclusions drawn from the findings in this study.

4. Years of careful study by many investigators has confirmed the fact that the causes of surgical wound infections are multifactorial. This fact, on the one hand, makes it necessary that an attempt be made by the investigators to control all factors, leaving the factor under study as the only variable, an almost impossible task, considering the multivariate nature of the problem. At the very least, the authors should have acknowledged the complexity of the problem by subjecting any investigative results to multifactorial analysis.

About a decade ago, while engaged in studies on the effect of moist bacterial strike-through of surgical apparel and drapes on the incidence of wound infection [1–3], we found it necessary to devise bench tests because of the inaccuracies that we found to creep into any clinical or statistical study of wound infections because of the literally hundreds of variables. The number of these variables, estimated as at least 155, made it virtually impossible to separate out one factor to evaluate, be it gowns, masks, or surgical techniques.

It became necessary, first, for us to attempt to organize the multitude of factors having some potential effect on the occurrence of surgical wound infection. This could only be done by qualitatively (not quantitatively) collating our observations with those reported in the literature, and grouping the factors under 5 main headings which were labeled "The Five D's of Surgical Infection Control: Discipline, Defense Mechanisms, Drugs, Design, and Devices" [4]. As one can see from Table 1, masks are but one of a long list of devices listed under aseptic barriers used in surgery. The discipline exercised by the user in the use of any and all devices in surgery is as important as the device itself. Most important, the table reflects the futility of attempting to determine the effect of any one of these variables without controlling the rest. We found the only way was to go to bench tests to verify any conclusions. Tunevall did not employ any bench tests to substantiate his quasi-statistical analysis from which he concluded that masks are of little value. Had he done so, his thesis could be defended only if the pathogens cultured from infected wounds did not match those found in the nasopharynx, or on the faces or hair of the surgical team involved.

Because the article has so little scientific validity, I do not believe many readers of it would feel justified to abandon the practice of wearing a surgical mask. I am surprised that neither the author nor the invited commentator, let alone the editor, made any comments along these lines. But bravo to Dr. Bessey, the

Table 1. The five D's of surgical infection control.

Discipline	Defense mechanisms	Drugs	Design	Devices
Surgeon's technique	Type of patient	Antibiotics	Configuration of surgical suite	Aseptic barriers
Type of operation	Age	Prophylactic	Central core	Gloves
Length of operation	Immune mechanisms	Preventive	Peripheral corridor	Clothing
Contact errors	Anatomic operative site	Therapeutic	Cluster plan	Drapes
OR team breaks	Obesity	Skin preparation	Central corridor	Masks
Scrub-procedure breaks	Malnourishment	Irrigation solutions	Location of CSR	Mechanical devices
Touch-contamination	Anemia		On-site recycling	Air handling
Overall technique breaks	Type of operation		Ceiling design	HVAC
Anesthesiologist	Foreign body implant		Presence of tracks	Gases and vacuum
Breaks	Organ transplant		Location of services	Anesthesia equipment
Attire and preparation	Effects of immunosuppressive drugs		Air grilles	Sterilization devices
Technique			Lighting	High vacuum
Errors contributing to airborne transmission	Effects of irradiation		Ambient	Steam
	Bacterial type, virulence, and number		Surgical	Gas–EO
Faulty containment			Cabinetry	Transport mechanisms
Hair and skin			Ventilation	Case carts vs. supply carts
Carrier potential			Pass-through	On-site inventory
Shedding potential			Open vs. closed	
Support services			Materials and surfaces	
Sterilization techniques			Storage space	
Maintenance and repair			Amount	
Standards and policies			Location	
Infection control nurse			Internal design	
Infection Control Committee			Traffic patterns	
Infection reporting and recording				
Statistics keeping				

invited commentator, for at least pointing out that masks may be as much a protection for the wearer as for the surgical patient.

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Reply

I am replying to the comments made by Harold Laufman, M.D., concerning my article, "Postoperative Wound Infections and Surgical Face Masks: A Controlled Study" (World J. Surg. *15*:383, 1991). There have been many comments on my investigations on the routine use of surgical face masks during general surgical procedures. Up to now the reactions have been mainly positive. Laufman is well known for his research and interest in surgical infections and I am well aware of the multitude of risk factors he mentions. There is no doubt that the surgeon and his assistants can be protected by the use of face masks. But Laufman obviously believes that the use of surgical face masks protects the patients from infections. I no longer believe this.

The etiology of postoperative wound infections is indeed multifactorial. Of course, I wish I had the resources to control all of the factors and make the immense statistical evaluation needed to ascertain the relative importance of each of them. Unfortunately, the different risk factors are not simply additive. Diabetes, for instance, ranges from a well controlled disease without any increased risk, to the high risks in complicated and unstable diabetes. Bacterial contamination ranges from zero to high numbers of several different bacteria with different virulence, and so on. The fact that controlling all the risk factors is "an almost impossible task", as Laufman puts it, must not stop us from doing clinical studies in this field.

The spectacular decrease in infection rates by half, reported by Orr in his uncontrolled material, had to be investigated. He had an on-going registration of his wound infection rates and after abandoning face masks the infection rate fell from 4% to 2%. In an attempt to confirm that the fall in the infection rate was due to the abandonment of face masks, I planned my study. During a 2 year period I estimated to include 3000 patients, which would reveal any 30% or greater difference, either way. Randomization of more than 3000 patients in 2 groups, one test group operated without face masks and one control group operated in the old way, with face masks, is enough to ascertain that most of the other (155?) risk factors are equally distributed in the two groups. This was the case when sex, age and type of operation was reviewed after the study. This is what is to be expected in a large randomized study.

I do not believe in doing bench tests to evaluate postoperative risks, but in another study to be published, I will describe the bacterial findings in the air within 20 cm from the wound during periods of the same operations, with the same staff, with and without face masks. No difference in the numbers of pathogens were found.

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